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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/555,987 09/11/00 VANDEN HEUVEL

J 7024465PUR99

EXAMINER

HM22/0620

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ART UNIT

PAPER NUMBER

1617

DATE MAILED:

06/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Application No.

09/555,987

Applicant(s)

VANDEN HEUVEL ET AL.

Examiner

San-ming Hui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

## **DETAILED ACTION**

### ***Claim Objections***

Claims 9 and 10 objected to because of the following informalities: the claims recite the term "CLA" in first line respectively; however, the base claim, claim 1, recites the term "conjugated linoleic acid". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isomers of conjugated linoleic acid (CLA) listed in specification, page 9, line 11-29, does not reasonably provide enablement for any esters or other geometric isomers of the CLA. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In the instant application, There is no adequate direction provided by the applicant as to how to select any other suitable CLA esterified compounds or other CLA isomers to be used in the invention to treat diabetes. Furthermore, the instant specification does not provide any working examples to show how any other CLA compounds besides the ones disclosed in the specification page 9, line 11 to 29, may be used in the invention to treat diabetes.

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Moreover, it is known in the art that different compounds may have different chemical and physical properties and therefore also different in potency and activity because of the structural and conformational differences in the compounds. Therefore a different CLA compound other than the linoleic acid compounds disclosed in specification page 9, line 11-29, may be reasonably expected to yield a different therapeutic result in treating disease such as diabetes. Due to this unpredictability of compound activity, it would prevent the skilled artisan from determining compounds which may be termed an "conjugated linoleic acid" to retain the desired function of the instant invention to treat diabetes without undue experimentation.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Boer et al. (US Patent 5,518,751) in view of Satter et al. (US Patent 5,770,247 from the Information Disclosure Statement received March 30, 2001).

de Boer et al. teaches that CLA in food compositions such as milk products are useful in treating diabetes (See particularly col. 1, line 35 to 43).

de Boer et al. does not expressly teach that the conjugated linoleic acid is *trans,cis*-9,11-octadecadienoic acid, *cis,cis*-9,11-octadecadienoic acid, or *trans,cis*-10,12-

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octadecadienoic acid. de Boer et al. does not expressly teach that the amount of the conjugated linoleic acid is about 1mg to about 10,000mg/kg of body weight in the invention.

Satter et al. teaches a method of adding linoleic acid compounds into milk (see particularly claim 1). Satter et al. also teaches the linoleic acid compounds to be used may include *trans,cis*-9,11-octadecadienoic acid or *cis,cis*-9,11-octadecadienoic acid or *trans,cis*-10,12-octadecadienoic acid (See particularly col. 5, line 51 to col.6 line 50).

It would have been obvious for one of ordinary skill in the art at the time the invention was made to incorporate about 1mg to about 10,000mg/kg of body weight of the *trans,cis*-9,11-octadecadienoic acid or *cis,cis*-9,11-octadecadienoic acid or *trans,cis*-10,12-octadecadienoic acid into a milk composition product useful in a method of treating diabetes.

One of ordinary skill in the art would have been motivated to incorporate the CLA compounds herein in the amounts herein into milk food composition products useful in a method of treating diabetes because CLAs, broadly, are known to be useful in a method and composition for treating diabetes. Therapeutic effects in the treatment of diabetes would have been reasonably expected when using any particular known CLA compounds including the compounds herein in a composition or method to treat diabetes.

Optimization of result effect parameters (e.g., amount and concentrations of composition ingredients to be employed) is obvious as being within the skill of the artisan.

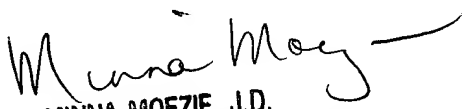
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Monday to Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui  
June 14, 2001

  
MINNA MOEZIE, J.D.  
SUPERVISORY PATENT EXAMINER  
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